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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/421,213    10/20/99    O'BRIEN    T    D6064CIP

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HM22/0629

EXAMINER

HARRIS, A

ART UNIT	PAPER NUMBER
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1642

10

DATE MAILED:

06/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/421,213**

Applicant(s)

**O'Brien And Tanimoto**

Examiner  
**Alana M. Harris, Ph. D.**

Group Art Unit  
**1642**



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-52 is/are pending in the application.  
Of the above, claim(s) 1-21 and 25-52 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 22-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election without traverse of Group V (claims 22-24) in Paper No. 9 is acknowledged.
2. Claims 1-52 are pending.  
Claims 1-21 and 25-52, drawn to non-elected inventions are withdrawn from examination.  
Claims 22-24 are examined on the merits.

### ***Oath/Declaration***

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it does not include the inventors' signatures.

### ***Drawings***

4. The drawings are objected to because of reasons cited on attached form PTO-948 completed by draftsman. Correction is required.

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*Specification*

5. The abstract does not reference the claimed invention in the instant application. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect that the claimed invention is drawn to a kit comprising an antibody.

7. The disclosure is objected to because of the following informality: the brief description of the figures lack a separate brief description of Figure 12-1 and Figure 12-2. Appropriate correction is required.

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***Claim Rejections - 35 U.S.C. § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitation "TADG-15" in claims 22 and 24 is vague and indefinite. "TADG-15" is an abbreviation whose identity is not well known in the art. The applicant is advised to amend the claims to include additional identifying characteristics such as "SEQ. ID. No: 1".

b. The recitation "fragment thereof" in claims 22 and 24 is vague and indefinite. It is not clear what is encompassed by the fragment. Is the fragment a portion of the heavy or light chain or absent of a constant region? Accordingly, it is impossible to determine the metes and the bounds of the claimed invention.

***Claim Rejections - 35 U.S.C. § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession #W22987 (October 8, 1997), in view of Lerner (Nature 299:592-596, 1982). Accession # W22987 teaches a polypeptide sequence comprising a fragment of the amino acid sequence of the TADG-15 protein. Accession # W22987 does not teach purified antibodies which specifically bind specified polypeptides, a means to detect said antibody, nor a kit.

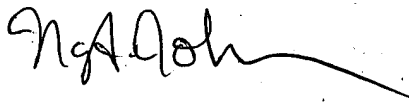
However, Lerner teaches that antibodies can be generated against peptides of at least 15 amino acids; representative of virtually any part of the surface of a protein can elicit antibodies reactive with the native molecule. It would have been *prima facie* to one of ordinary skill in the art at the time the claimed invention was made to select specific regions of the polypeptide of Accession # W22987 or the entire fragment in order to produce antibodies reactive with said TADG-15 protein, as taught in Lerner. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Lerner, that such antibodies are powerful aids in the study of the polypeptide.

In addition, although the claims recite a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the reference read on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and methods of detection, diagnostics and therapies also were well known and available to the ordinarily skilled artisan. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.  
Patent Examiner, Group 1642  
June 26, 2000

  
NANCY A. JOHNSON, PH.D  
PRIMARY EXAMINER